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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/673.007

09/26/2003

Carlos F. Ibanez

LCTD-0006

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06/22/2006

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT

PAPER NUMBER

1649

DATE MAILED: 06/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/673,007

Applicant(s)

IBANEZ ET AL.

Examiner

Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 12-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-9 and 12-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 22, 24 & 28, drawn to the rat GDNF receptor protein of SEQ ID NO: 2, classified in class 530, subclass 350.
 - II. Claims 1, 23, 25 & 28, drawn to the human GDNF receptor protein of SEQ ID NO: 9, classified in class 530, subclass 350.
 - III. Claim 26, drawn to nucleic acids encoding a rat GDNF receptor protein of SEQ ID NO: 5, classified in class 536, subclass 23.5.
 - IV. Claim 27, drawn to nucleic acids encoding a human GDNF receptor protein of SEQ ID NO: 10, classified in class 435, subclass 69.1.
 - V. Claims 2-9, drawn to methods for identifying compounds which bind to GDNF receptors, classified in Class 536, subclass 23.5.
 - VI. Claims 12-13 & 18-19, drawn to methods for identifying GDNF homologs that bind to c-RET receptors and effect c-fos mRNA levels, classified in Class 435, subclass 6.
 - VII. Claims 14-15 & 20-21, drawn to methods for identifying GDNF homologs that bind to c-RET receptors and increase cell survival, classified in Class 435, subclass 7.21.
 - VIII. Claims 16-17, drawn to methods for identifying GDNF analogs which bind to c-RET receptors and increase tyrosine phosphorylation, classified in Class 435, subclass 7.2.

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2. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper, because these products appear to constitute patentably distinct inventions for the following reasons:

Groups I-IV are directed to products that are physically and functionally distinct involving proteins and nucleic acids. Each of these products can be prepared by different processes, such as through chemical synthesis or isolation from natural sources using various isolation/purification procedures. For example, the proteins of Groups I-II are fundamentally different molecules than the nucleic acid molecules of Groups III-IV, which in turn can be used to clone proteins, detect cells that express the protein, or used as therapeutic agents in gene therapy. In contrast, the proteins of Groups I-II can be utilized in making antibodies or used in affinity chromatography. Lastly, the proteins of Groups I & II, and the nucleic acids that encode such of Groups III & IV, are distinct as illustrated by their unique structures and unique SEQ ID NOs, and vice versa. It is pointed out that there is a proper distinction between these groups, since each product is not required in order for the other to exist. Thereby, these groups are distinct and separable for the reasons stated.

Groups I-II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the proteins of Groups I-II can be

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used in other materially different methods, such as in affinity chromatography for isolating GDNF analogs, to generate antibodies, or for potentially treating patients with these receptor molecules. In contrast, the method of identifying compounds that bind GDNF receptors require test compounds, and assay protocols, none of which are required in the products of Groups I-II.

It is noted that the methods of Group V do not require the products of Groups III-IV, and vice versa.

Although there are no provisions under the section for "Relation of Inventions" in M.P.E.P. 806.05 for inventive groups that are directed to different methods, restriction is deemed proper because these methods appear to constitute patently distinct inventions for the following reasons:

Groups V-VIII are directed to methods for identifying compounds which bind to GDNF receptors or to c-Ret receptors, respectively, involving either binding reactions, c-fos mRNA level assays, cell survival or tyrosine phosphorylation assays, respectively. Each of these methods requires physically and functionally distinct elements, and have different goals, starting materials, and method steps. These inventions are, therefore, patentably distinct, since one is not required for the other.

Because these inventions are distinct for the reasons given above, they have acquired a separate status in the art as shown by their different classification, and the non-coextensiveness of the search and examination for each group would constitute an undue burden on the examiner to search and consider all the separable groups with their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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3. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

4. Lastly, note that *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996) addressed the issue of whether an otherwise conventional process could be patented if it were limited to making or using a nonobvious product.

In situations where product and process claims drawn to independent and distinct inventions are presented in the same application, an applicant may be called upon under 35 U.S.C. §121 to elect claims to either the product or process. The claims to the non-elected invention will be withdrawn from further consideration. However, in the case of an elected product claim, when a product claim is found allowable, withdrawn process claims which depend from or otherwise include all the limitations of an allowable product claim will be rejoined. Withdrawn process claims not commensurate in scope with an allowable product claim will not be rejoined. In the event of rejoinder, the rejoined process claims will be fully examined for patentability. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to be 'RCH' with a stylized flourish.

Robert C. Hayes, Ph.D.
June 14, 2006

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER